

Controller Medications for Asthma

Key Questions and Inclusion Criteria

Update #1

Key Questions

1. What is the comparative efficacy and effectiveness of controller medications used to treat outpatients with persistent asthma?
2. What is the comparative tolerability and frequency of adverse events for controller medications used to treat outpatients with persistent asthma?
3. Are there subgroups of these patients based on demographics (age, racial groups, gender), asthma severity, comorbidities (drug-disease interactions, including obesity), other medications (drug-drug interactions), smoking status, genetics, or pregnancy for which asthma controller medications differ in efficacy, effectiveness, or frequency of adverse events?

Inclusion Criteria

Populations

- Adult or pediatric outpatients with persistent asthma.

Interventions

Drug Type	Generic Name	Trade Name	Forms
Inhaled Corticosteroids	Beclomethasone	Qvar® ^a Vanceril® ^c	Inhaled Inhaled
	Budesonide	Pulmicort Turbuhaler® ^c Pulmicort Flexhaler® ^b Pulmicort Respules® ^b Pulmicort Nebuamp® ^a	Inhaled Inhaled Inhaled Inhaled
	Flunisolide	AeroBid® ^b AeroBid-M® ^b AeroSpan® ^b Bronalide® ^c	Inhaled Inhaled Inhaled Inhaled
	Fluticasone	Flovent® ^c Flovent Rotadisk® ^c Flovent Diskus® ^c Flovent HFA® ^a	Inhaled Inhaled Inhaled Inhaled
	Triamcinolone	Azmacort® ^b	Inhaled
	Mometasone	Asmanex Twisthaler® ^b	Inhaled
	Ciclesonide	Alvesco® ^{a, f}	Inhaled
Long-Acting beta-2 agonists (LABAs)	Formoterol	Foradil® ^c Foradil Certihaler® ^b Foradil Aerolizer® ^b Oxis® ^d Perforomist® ^b Oxeze Turbuhaler® ^c	Inhaled Inhaled Inhaled Inhaled Inhaled Inhaled
	Arformoterol	Brovana® ^b	Inhaled
	Salmeterol	Serevent® ^c Serevent Diskhaler® ^c Serevent Diskus® ^a	Inhaled Inhaled Inhaled

Drug Type	Generic Name	Trade Name	Forms
Leukotriene Modifiers (leukotriene receptor antagonists (LTRAs) and leukotriene synthesis inhibitors (LTSIs))	Montelukast	Singulair® ^a	Tablets, Chewable tablets, Granules
	Zafirlukast	Accolate® ^a	Tablets
	Zileuton	Zyflo® ^b ZyfloCR® ^b	Tablets Extended release tablets
Anti-IgE Therapy	Omalizumab	Xolair® ^a	Powder for subcutaneous injection
Combination Products	Fluticasone propionate/Salmeterol xinafoate	Advair® ^a Advair Diskus® ^a Advair HFA® ^b	Inhaled Inhaled Inhaled
	Budesonide/formoterol	Symbicort® ^b Symbicort Turbuhaler® ^c	Inhaled Inhaled
Long-Acting anticholinergics	Tiotropium	Spiriva® ^{a,f}	Inhaled

^a Product is available in the US and Canada; ^b Product is not available in Canada; ^c Product is available in Canada only; ^d Product is not available in the US or Canada; ^e Product has been discontinued by the manufacturer; ^f Product is new on the list since the last report

Efficacy and Effectiveness Outcomes

- Control of symptoms (e.g., days/nights/frequency of symptoms, rate of asthma exacerbations, frequency of rescue medication use, courses of oral steroids)
- Functional capacity and quality of life (missed school and missed work days, ability to participate in work/school/sports/physical activity, activity limitation, improved sleep/sleep disruption)
- Urgent care services (Emergency department visits/urgent medical care visits)
- Adherence
- Hospitalization
- Mortality

Safety Outcomes

- Overall adverse events reported
- Withdrawals due to adverse events
- Serious adverse events reported (e.g., growth suppression, hypothalamus-pituitary-adrenal axis suppression, osteoporosis/fractures, mortality)
- Specific adverse events or withdrawals due to specific adverse events (e.g. growth retardation, bone mineral density, ocular toxicity, suppression of the HPA axis, tachycardia, anaphylaxis, death)

Study Designs

- For efficacy and effectiveness: randomized controlled trials of at least 6 weeks duration (n ≥ 40) and good-quality systematic reviews
- For safety: randomized controlled trials of at least 6 weeks (n ≥ 40), good-quality systematic reviews, and observational studies of at least 6 months duration (n ≥ 100)